

1 CLAIMS

2 What is claimed is:

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4 Claim 1. A biopolymer marker selected from the group  
5 consisting of sequence ID (-)XSVLTQPPSVSGAPGQR(V),  
6 (K)YAASSYLSLTPEQWK(S), (K)SGTASVVCLLNNFYPR(E),  
7 (K)GLEWVAGLSWNSDNIR(Y), (R)THSGEKYVCRECRGFSQK(S),  
8 (R)HIALSPRYLNRKR(T), (R)AGYRIDSWGQGTTLVT(-) or at least one  
9 analyte thereof useful in indicating at least one  
10 particular disease state.

11  
12 Claim 2. The biopolymer marker of claim 1 wherein  
13 said disease state is predictive of Alzheimers disease.

14  
15 Claim 3. A method for evidencing and categorizing at  
16 least one disease state comprising:

17 obtaining a sample from a patient;

18 conducting mass spectrometric analysis on said

19 sample;

20 evidencing and categorizing at least one biopolymer  
21 marker sequence or analyte thereof isolated from said  
22 sample; and,

23 comparing said at least one isolated biopolymer  
24 marker sequence or analyte thereof to the biopolymer

1 marker sequence as set forth in claim 1;  
2 wherein correlation of said isolated biopolymer  
3 marker and said biopolymer marker sequence as set forth in  
4 claim 1 evidences and categorizes said at least one  
5 disease state.

6  
7 Claim 4. The method of claim 3, wherein said step  
8 of evidencing and categorizing is particularly directed to  
9 biopolymer markers or analytes thereof linked to at least  
10 one risk of disease development of said patient.

11  
12 Claim 5. The method of claim 3, wherein said step  
13 of evidencing and categorizing is particularly directed to  
14 biopolymer markers or analytes thereof related to the  
15 existence of a particular disease state.

16  
17 Claim 6. The method of claim 3, wherein the sample  
18 is an unfractionated body fluid or a tissue sample.

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20  
21 Claim 7. The method of claim 3, wherein said sample  
22 is at least one of the group consisting of blood, blood  
23 products, urine, saliva, cerebrospinal fluid, and lymph.

1           Claim 8. The method of claim 3, wherein said mass  
2   spectrometric analysis is selected from the group  
3   consisting of Surface Enhanced Laser Desorption Ionization  
4   (SELDI) mass spectrometry (MS), Maldi Qq TOF, MS/MS,  
5   TOF-TOF, and ESI-Q-TOF or an ION-TRAP.

6  
7           Claim 9. The method of claim 3, wherein said  
8   patient is a human.

9  
10          Claim 10. A diagnostic assay kit for determining  
11   the presence of the biopolymer marker or analyte thereof  
12   of claim 1 comprising:

13          at least one biochemical material which is capable of  
14   specifically binding with a biomolecule which includes at  
15   least said biopolymer marker or analyte thereof, and

16          means for determining binding between said  
17   biochemical material and said biomolecule;

18          whereby at least one analysis to determine a presence  
19   of a marker, analyte thereof, or a biochemical material  
20   specific thereto, is carried out on a sample.

21  
22          Claim 11. The diagnostic assay kit of claim 10,  
23   wherein said biochemical material or biomolecule is  
24   immobilized on a solid support.

1           Claim 12. The diagnostic assay kit of claim 10  
2 including:

3           at least one labeled biochemical material.  
4

5           Claim 13. The diagnostic assay kit of claim 10,  
6 wherein said biochemical material is an antibody.  
7

8           Claim 14. The diagnostic assay kit of claim 12,  
9 wherein said labeled biochemical material is an antibody.  
10

11          Claim 15. The diagnostic assay kit of claim 10,  
12 wherein the sample is an unfractionated body fluid or a  
13 tissue sample.  
14

15          Claim 16. The diagnostic assay kit of claim 10,  
16 wherein said sample is at least one of the group  
17 consisting of blood, blood products, urine, saliva,  
18 cerebrospinal fluid, and lymph.  
19

20          Claim 17. The diagnostic assay kit of claim 10,  
21 wherein said biochemical material is at least one  
22 monoclonal antibody specific therefore.  
23

24          Claim 18. A kit for diagnosing, determining risk-

1 assessment, and identifying therapeutic avenues related to  
2 a disease state comprising:

3 at least one biochemical material which is capable of  
4 specifically binding with a biomolecule which includes at  
5 least one biopolymer marker selected from the group  
6 consisting of sequence ID (-)XSVLTQPPSVSGAPGQR(V),  
7 (K)YAASSYLSLTPEQWK(S), (K)SGTASVVCLLNNFYPR(E),  
8 (K)GLEWVAGLSWNSDNIR(Y), (R)THSGEKYVCRECRRGFSQK(S),  
9 (R)HIALSPRYLNRKR(T), (R)AGYRIDSWGQGTTLVT(-) or at least one  
10 analyte thereof related to said disease state; and

11 means for determining binding between said  
12 biochemical material and said biomolecule;

13 whereby at least one analysis to determine a presence  
14 of a marker, analyte thereof, or a biochemical material  
15 specific thereto, is carried out on a sample.

16  
17 Claim 19. The kit of claim 18, wherein said  
18 biochemical material or biomolecule is immobilized on a  
19 solid support.

20  
21 Claim 20. The kit of claim 18 including:  
22 at least one labeled biochemical material.

23  
24 Claim 21. The kit of claim 18, wherein said

1 biochemical material is an antibody.

2  
3 Claim 22. The kit of claim 20, wherein said labeled  
4 biochemical material is an antibody.

5  
6 Claim 23. The kit of claim 18, wherein the sample is  
7 an unfractionated body fluid or a tissue sample.

8  
9 Claim 24. The kit of claim 18, wherein said sample  
10 is at least one of the group consisting of blood, blood  
11 products, urine, saliva, cerebrospinal fluid, and lymph.

12  
13 Claim 25. The kit of claim 18, wherein said  
14 biochemical material is at least one monoclonal antibody  
15 specific therefore.

16  
17 Claim 26. The kit of claim 18, wherein said  
18 diagnosing, determining risk assessment, and identifying  
19 therapeutic avenues is carried out on a single sample.

20  
21 Claim 27. The kit of claim 18, wherein said  
22 diagnosing, determining risk assessment, and identifying  
23 therapeutic avenues is carried out on multiple samples  
24 such that at least one analysis is carried out on a first

1 sample and at least another analysis is carried out on a  
2 second sample.

3  
4 Claim 28. The kit of claim 27, wherein said first  
5 and second samples are obtained at different time periods.

6  
7 Claim 29. Polyclonal antibodies produced against a  
8 marker sequence ID selected from the group consisting of  
9 sequence ID (-)XSVLTQPPSVSGAPGQR(V),  
10 (K)YAASSYLSLTPEQWK(S), (K)SGTASVVCLLNNFYPR(E),  
11 (K)GLEWVAGLSWNSDNIR(Y), (R)THSGEKYVCRECRRGFSQK(S),  
12 (R)HIALSPRYLNRKR(T), (R)AGYRIDSWGQGTLVT(-) or at least one  
13 analyte thereof in at least one animal host.

14  
15 Claim 30. An antibody that specifically binds a  
16 biopolymer including a marker selected from the group  
17 consisting of sequence ID (-)XSVLTQPPSVSGAPGQR(V),  
18 (K)YAASSYLSLTPEQWK(S), (K)SGTASVVCLLNNFYPR(E),  
19 (K)GLEWVAGLSWNSDNIR(Y), (R)THSGEKYVCRECRRGFSQK(S),  
20 (R)HIALSPRYLNRKR(T), (R)AGYRIDSWGQGTLVT(-) or at least one  
21 analyte thereof.

22  
23 Claim 31. The antibody of claim 30 that is a  
24 monoclonal antibody.

Claim 32. The antibody of claim 30 that is a polyclonal antibody.

Claim 33. A process for identifying therapeutic avenues related to a disease state comprising:

conducting an analysis as provided by the kit of claim 18; and

interacting with a biopolymer selected from the group consisting of sequence ID (-)XSVLTPPPSVSGAPGQR(V), (K)YAASSYLSLTPEQWK(S), (K)SGTASVVCLLNNFYPR(E), (K)GLEWVAGLSWNSDNIR(Y), (R)THSGEKYVCRECRRGFSQK(S), (R)HIALSPRYLNRKR(T), (R)AGYRIDSWGQGTTLVT(-) or at least one analyte thereof;

whereby therapeutic avenues are developed.

Claim 34. The process for identifying therapeutic avenues related to a disease state in accordance with claim 33, wherein said therapeutic avenues regulate the presence or absence of the biopolymer selected from the group consisting of sequence ID (-)XSVLTQPPSVSGAPGQR(V), (K)YAASSYLSLTPEQWK(S), (K)SGTASVVCLLNMFYPR(E), (K)GLEWVAGLSWNSDNIR(Y), (R)THSGEKYVCRECRRGFSQK(S), (R)HIALSPRYLNRKR(T), (R)AGYRIDSWGQGTTLVT(-) or at least one



1     analyte thereof.

2

3           Claim 35.     The process for identifying therapeutic  
4     avenues related to a disease state in accordance with  
5     claim 33, wherein said therapeutic avenues developed  
6     include at least one avenue selected from a group  
7     consisting of 1)utilization and recognition of said  
8     biopolymer markers, variants or moieties thereof as direct  
9     therapeutic modalities, either alone or in conjunction  
10    with an effective amount of a pharmaceutically effective  
11    carrier; 2)validation of therapeutic modalities or disease  
12    preventative agents as a function of biopolymer marker  
13    presence or concentration; 3)treatment or prevention of a  
14    disease state by formation of disease intervention  
15    modalities; 4)use of biopolymer markers or moieties  
16    thereof as a means of elucidating therapeutically viable  
17    agents, 5)instigation of a therapeutic immunological  
18    response; and 6) synthesis of molecular structures related  
19    to said biopolymer markers, moieties or variants thereof  
20    which are constructed and arranged to therapeutically  
21    intervene in said disease state.

22

23           Claim 36.     The process for identifying therapeutic  
24    avenues related to a disease state in accordance with

1 claim 35, wherein said treatment or prevention of a  
2 disease state by formation of disease intervention  
3 modalities is the formation of biopolymer/ligand  
4 conjugates which intervene at receptor sites to prevent,  
5 delay or reverse a disease process.

6  
7 Claim 37. The process for identifying therapeutic  
8 avenues related to a disease state in accordance with  
9 claim 35, wherein said means of elucidating  
10 therapeutically viable agents includes use of a  
11 bacteriophage peptide display library or a bacteriophage  
12 antibody library.

13  
14 Claim 38. A process for regulating a disease state  
15 by controlling the presence or absence of a biopolymer  
16 selected from the group consisting of sequence ID (-  
17 )XSVLTQPPSVSGAPGQR(V), (K)YAASSYLSLTPEQWK(S),  
18 (K)SGTASVVCLLNNFYPR(E), (K)GLEWVAGLSWNSDNIR(Y),  
19 (R)THSGEKYVCRECRRGFSQK(S), (R)HIALSPRYLNRKR(T),  
20 (R)AGYRIDSWGQGTTLVT(-) or at least one analyte thereof.